CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-690

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-690

Ortho-McNeil Pharmaceutical, Inc.
Johnson & Johnson Pharmaceutical Research & Development, L.L.C., US Agent
Attention: Tracy Healy, RN, MBA
Manager, Regulatory Affairs, Global Marketed Products
920 Route 202 South, P.O. Box 300
Raritan, New Jersey 08869-0602

Dear Ms. Healy:

Please refer to your new drug application (NDA) dated September 24, 2003, received September 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ortho Tri-Cyclen® (norgestimate/ethinyl estradiol) Tablets.

We acknowledge receipt of your submissions dated April 14 and November 18, 2004, January 21, April 19, and May 3, 2005.

The November 18, 2004 submission constituted a complete response to our March 23, 2004 action letter.

This new drug application provides for revision to the **Pediatric Use** subsection of the **PRECAUTIONS** section of the prescribing information for Ortho TriCyclen to incorporate the results from the CAPPS-169 study entitled "The Effect of Ortho TriCyclen on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa".

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We note that you agreed to this revised labeling in your May 3, 2005 submission and in the telephone conversation on May 9, 2005, between yourself and Pat Madara from this division.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-690**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html.
All communications regarding this application that contain electronic media or a combination of electronic and paper media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

Paper communications regarding this application that **DO NOT** contain electronic media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 8B45
5600 Fishers Lane
Rockville, Maryland 20857

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 19-697 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert